

DEC 12 2003

K033404

Summary of Safety and Effectiveness
Liquichek Urine Toxicology Control (Confirmatory Series)

1.0 **Submitter**

Bio-Rad Laboratories
9500 Jeronimo Road,
Irvine, California 92618-2017
Telephone: (949) 598-1200
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Contact Person

Maria Zeballos
Regulatory Affairs Specialist
Telephone: (949) 598-1367

Date of Summary Preparation

October 22, 2003

2.0 **Device Identification**

Product Trade Name:	Liquichek Urine Toxicology Control
	<input type="checkbox"/> Liquichek Urine Toxicology Control Level C1
	<input type="checkbox"/> Liquichek Urine Toxicology Control Level C2
	<input type="checkbox"/> Liquichek Urine Toxicology Control Level C3
	<input type="checkbox"/> Liquichek Urine Toxicology Control Level C4
	<input type="checkbox"/> Liquichek Urine Toxicology Control Level C2 Low Opiate
	<input type="checkbox"/> Liquichek Urine Toxicology Control Level C3 Low Opiate
Common Name:	Drug Mixture Control
Classifications:	Class I
Product Code:	DIF
Regulation Number:	21 CFR 862.3280

3.0 **Device to Which Substantial Equivalence is Claimed**

Liquichek Urine Toxicology Control Levels C1, C2, C3 and C4
Bio-Rad Laboratories
Irvine, California
Docket Number: K021384

4.0 **Description of Device**

Liquichek Urine Toxicology Controls are prepared from human urine with added drugs of abuse, metabolites of drugs of abuse, preservatives, stabilizers and constituents of animal origin. The control is provided in liquid form for convenience.

5.0 **Statement of Intended Use**

Liquichek Urine Toxicology Control is intended for use as a quality control urine to monitor the performance of laboratory urine toxicology confirmatory procedures.

6.0 Comparison of the new device with the Predicate Device

The new Liquichek Urine Toxicology Control contains 3,4-Methylenedioxy-methamphetamine (MDMA), 3,4-Methylenedioxyamphetamine (MDA) and 3,4-Methylenedioxy-N-ethylamphetamine (MDEA) in levels C2, C3 and C4 , and the currently marketed Liquichek Urine Toxicology Control (K021384) to which substantial equivalence is claimed does not contain these analytes.

Table 1. Similarities and Differences between new and predicate device.

Characteristics	Bio-Rad Liquichek Urine Toxicology Control (Confirmatory Series) (New Device)	Bio-Rad Liquichek Urine Toxicology Control Levels C1, C2, C3 and C4 (Predicate Device K021384)
Similarities		
Intended Use	Liquichek Urine Toxicology Control is intended for use as a quality control urine to monitor the performance of laboratory urine toxicology confirmatory procedures.	Liquichek Urine Toxicology Control is intended for use as a quality control urine to monitor the performance of laboratory urine toxicology confirmatory procedures.
Form	Liquid	Liquid
Matrix	Urine	Urine
Storage (Unopened)	2 to 8°C until expiration date	2 to 8°C until expiration date
Open Vial	30 days at 2 to 8°C	30 days at 2 to 8°C
Differences		
Drugs	Same as the predicate device with the addition in Levels C2, C3 and C4 of: 3,4-Methylenedioxymethamphetamine (MDMA), 3,4-Methylenedioxyamphetamine (MDA) and 3,4-Methylenedioxy-N-ethylamphetamine (MDEA)	11-Nor-Δ ⁹ -THC-9-COOH, Alpha-Hydroxyalprazolam, Amobarbital, d-Amphetamine, Benzoyllecgonine, Butalbital, Codeine, Ethanol, Lysergic Acid Diethylamide (LSD), d-Methamphetamine, Methadone, Methaqualone, Morphine-3-β-D-Glucuronide, Nordiazepam, Norpropoxyphene, Pentobarbital, Phencyclidine, Phenobarbital, Secobarbital <u>Does not contain:</u> 3,4-Methylenedioxymethamphetamine (MDMA), 3,4-Methylenedioxyamphetamine (MDA) and 3,4-Methylenedioxy-N-ethylamphetamine (MDEA)
Label Warnings	Does not require hazard symbols	Requires hazard symbols

7.0 Statement of Supporting Data

Stability studies have been performed to determine the open vial stability and shelf life for the Liquichek Urine Toxicology Control. Product claims are as follows:

- 7.1 Open vial: All analytes will be stable for 30 days when stored tightly capped at 2 to 8°C.
- 7.2 Shelf Life: 3 Years at 2 to 8°C
- 7.3 Real time studies will be ongoing to support the shelf life of this product.

All supporting data is retained on file at Bio-Rad Laboratories.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Maria Zeballos, RAC
Regulatory Affairs Specialist
Bio-Rad Laboratories, QSD
Diagnostics Group
9500 Jeronimo Road
Irvine, CA 92618-2017

DEC 12 2003

Re: k033404

Trade/Device Name: Liquichek Urine Toxicology Control Level C1
Liquichek Urine Toxicology Control Level C2
Liquichek Urine Toxicology Control Level C3
Liquichek Urine Toxicology Control Level C4
Liquichek Urine Toxicology Control Level C2 Low Opiate
Liquichek Urine Toxicology Control Level C3 Low Opiate

Regulation Number: 21 CFR 862.3280

Regulation Name: Clinical toxicology control material

Regulatory Class: Class I

Product Code: DIF

Dated: October 22, 2003

Received: October 29, 2003

Dear Ms. Zeballos:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

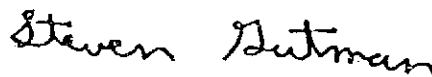
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive style with a large, stylized "G".

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

510 (k) Number (if known): K033 404

Device Name:

Liquichek Urine Toxicology Confirmatory Series Control

- ☐ **Liquichek Urine Toxicology Control Level C1**
- ☐ **Liquichek Urine Toxicology Control Level C2**
- ☐ **Liquichek Urine Toxicology Control Level C3**
- ☐ **Liquichek Urine Toxicology Control Level C4**
- ☐ **Liquichek Urine Toxicology Control Level C2 Low Opiate**
- ☐ **Liquichek Urine Toxicology Control Level C3 Low Opiate**

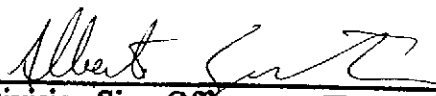
Indications for Use:

Liquichek Urine Toxicology Control is intended for use as a quality control urine to monitor the performance of laboratory urine toxicology confirmatory procedures.

(PLEASE DO NOT WRITE BELOW THE LINE-CONINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription use ✓ or Over-the Counter use _____


Division Sign-Off *for Jean Cooper*

**Office of In Vitro Diagnostic Device
Evaluation and Safety**

510(k) K033 404